

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

PAUL LUCIW et al.

Serial No: 08/089,407

Group Art Unit: 1813

Filed: July 8, 1993

Examiner: M. Woodward

For: HIV IMMUNOASSAYS USING SYNTHETIC ENVELOPE POLYPEPTIDES
(AS AMENDED)

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MATRIX CUSTOMER
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Assistant Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. The information listed includes that which was previously considered by a U.S. Examiner during the prosecution of applications from which this application takes priority, as well as newly cited information. There have been rejections during the prosecution of pending applications and a number of attacks on the validity of corresponding foreign patents and allowed applications. Rejections and other attacks have been made in the form of, inter alia, written argument, document citations and affidavits. While these attacks are believed to be without merit, it is believed by Applicants that this information should be submitted to the Examiner out of an abundance of caution. The best explanation of these attacks is believed to be found in the various written arguments, pleadings, opposition statements and witness statements that accompany the attacks. Relevant selections from Applicants' responsive pleadings, opposition replies, and witness statements that set out Applicants' views of the various statements are likewise submitted herewith.

The Examiner is respectfully requested to me all of this information of official record in the application. For the Examiner's convenience, the information has been organized as follows:

- I. DOCUMENTS CITED IN PRIOR RELATED APPLICATIONS:
- II. DOCUMENTS CITED IN OPPOSITION TO EUROPEAN PATENT 0 181 150-B RELATING TO THE PENDING APPLICATION:
- III. DOCUMENTS CITED IN LITIGATION NO. C934380; CHIRON CORPORATION V. ABBOTT LABORATORIES ON RELATED U.S. PATENT NO. 5,156,949:
- IV. OTHER RELATED DOCUMENTS: and
- V. SUMMARY:

I. DOCUMENTS CITED IN PRIOR APPLICATIONS:

The following documents were disclosed in related patent applications U.S. Serial No. 06/773,447 and U.S. Serial No. 07/138,894. Copies of the documents are not included as provided in 37 CFR §1.98(d). These documents, however, are listed on the attached PTO-1449 Form.

U.S. Patent No. 4,420,113, filed 5/28/85, to Gallo et al.
U.S. Patent No. 4,708,818, filed 11/24/87, to Montagnier
U.S. Patent No. 4,716,102, filed 12/29/87, to Levy
European Patent No. 0 136 798, published 4/10/85
European Patent No. 0 138 667, published 4/24/85
European Patent No. 0 139 216, published 5/2/85
European Patent No. 0 152 030, published 8/21/85
European Patent No. 0 165 120, published 12/18/85
European Patent No. 0 173 529, published 3/5/86
European Patent No. 0 178 978, published 4/23/86
European Patent No. 0 181 150; published 5/14/86
European Patent No. 0 184,444; published 6/25/86

PCT No. WO 85/04897, published 11/7/85
PCT No. WO 85/04903, published 11/7/85
PCT No. WO 86/02383, published 4/24/86
Alizon, et al., Nature, (1984) 312:757-760
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Sanchez-Pescador, et al., Science (1985) 227:484-492
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Saxinger, et al., Laboratory Investigation (1983) 49:371-377
Schupback, et al., Science (1984) 224:607-609
Shaw, et al., Science (1984) 226:1165-1171
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Sinkovics, et al., Reviews of Infectious Diseases (1984) 6:745-760
Vilmer, et al., Lancet (1984) 1:753
Wain-Hobson, S., AIDS 3 (Suppl. 1):S13-S18 (1989)

II. DOCUMENTS CITED IN EUROPEAN OPPOSITION (0 181 150-B):

The following documents were filed in opposition to related European Patent No. 0 181 150-B, which claims priority from U.S. Serial Nos. 06/667,501, filed October 31, 1984; 06/696,534, filed January 30, 1985; and 06/773,447, filed September 6, 1985. A copy of each of these documents is provided. In addition, these documents are listed on the attached PTO-1449 form.

Original Notice of Opposition by Abbott Laboratories filed June 11, 1993
Supplemental version of original Notice of Opposition by Abbott filed March 9, 1994
Notice of Opposition (plus English translation) by Biotest AG filed March 3, 1994
Notice of Opposition (plus English translation) by Hoffmann-La Roch AG filed March 7, 1994
Notice of Opposition by British Bio-Technology Ltd., filed March 8, 1994
Notice of Opposition by Murex Diagnostics Ltd., filed March 8, 1994
Notice of Opposition by Akzo Pharma BV filed March 9, 1994
Notice of Opposition by Viagene Inc., filed March 9, 1994
Notice of Opposition (plus English translation) by Behringwerke filed March 9, 1994
Notice of Opposition by Immuno AG filed March 9, 1994

Response to Oppositions by Chiron filed July 11, 1995

Observations by British Bio-Technology Ltd., filed January 25, 1996

The following previously uncited documents were cited in one or more of the above-cited papers filed in opposition to EP-B-0181150. A copy of each of these documents is provided. In addition, these documents are listed on the attached PTO-1449 form.

U.S. Serial No. 728,052, filed April 1, 1986

U.S. Serial No. 767,303, filed August 19, 1985

U.S. Serial No. 685,272, filed December 24, 1984

U.S. Serial No. 844,485, filed November 13, 1986

EP No. 0 060 057, published September 15, 1982

EP No. 0 073 635, published March 9, 1983

EP No. 0 088 632, published September 14, 1983

EP No. 0 116 201, published August 22, 1984

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EP No. 0 201 540, published November 20, 1986

EP No. 0 178 978, published February 6, 1992

PCT No. WO 86/02383, published April 24, 1986

PCT No. WO 86/06414, published November 6, 1986

PCT No. WO 84/16013, published October 18, 1984

PCT No. WO 84/23659, published September 19, 1984

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Chermann et al., in Gottlieb et al. (eds. 1984) "Acquired Immune Deficiency Syndrome" UCLA Symposia on Molecular Biology, News Series, Vol. 16 (1984) pp. 31-46 Clinical, Abstract (1984) p.9

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Dina et al., DNA (1985) 4(1):56

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Fisher et al., Nature (1985) 316:262-265

Fischinger et al., Cancer Research (1985) 45:4694s-4699s

French, T.J., First Declaration of T.J. French (1994)

Gallo et al., in Gottlieb et al. Eds. (1984) pp 47-58 "Acquired Immune Deficiency Syndrome" UCLA Symposia on Molecular Biology, New Series (1984) 16:47-58

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Hattori et al., Virology (1984) 136:338-347

Huang et al., DNA (1985) 4(1):70

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Peutherer et al., Med. Laboratory Sciences, (1981) 38:355-358

III. DOCUMENTS CITED IN LITIGATION NO. C 93 4380 MHP:

The following documents were either cited by one of the parties or filed in *Chiron v. Abbott Laboratories*, No. C93 4380 MHP. A copy of each of these documents is provided. In addition, these documents are listed on the attached PTO-1449 form. The supporting documentation are not attached to those documents submitted herein. Applicants offer to make any of the supporting documentation available to the Examiner upon request, subject to the Protective Order in force.

European Patent No. 0 020 251, published 12/10/80

European Patent No. 0 062 574, published 10/13/82

Expert Report of John A.T. Young, Ph.D. (redacted to remove confidential material)

Expert Report of B. Matija Peterlin, M.D.

Expert Report of Robin A. Weiss, Ph.D.

Amended Expert Report of Hans-Martin Jack, Ph.D.

Expert Report of Herman N. Eisen, Ph.D.

Amended Memorandum and Order Re Defense of Enablement by U.S. District Court Judge
Marilyn Patel, entered April 25, 1996.

Memorandum and Order Re Defense of Inequitable Conduct and Prior Invention by U.S. District Court Judge Marilyn Patel, entered September 19, 1995.

IV. OTHER RELATED DOCUMENTS:

In addition to the above documents, the following may also be material to the examination of this patent application. Copies of the information and completed PTO-1449 forms are submitted herewith.

Kleid *et al.*, *Science* (1981) 214:1125-1129

Laub *et al.*, *J. of Virology* (1983) 48:271-280

Valenzuela *et al.*, *Nature* (1982) 298:347-350

Watson *et al.*, *Science* (1982) 218:381-384

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Declaration of Dr. Rob H. Meloen, filed by United Biomedical Inc., in Opposition to European Patent No. 0 318 216-B to Chiron Corporation

V. SUMMARY:

Applicants request that the Examiner initial and return the form PTO-1449 indicating that the documents and materials provided herewith or in the cross-referenced earlier applications have indeed been considered and made of record herein.

This information disclosure statement under 37 CFR §1.56, §1.97 and §1.98 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, that the information, protocols, results etc. reported by third parties are accurate or enabling, or that these citations constitute prior art under 35 USC §102 or §103.

Please charge any fees or credit any overpayment to Deposit Account No. 03-1664.

Respectfully submitted,

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March 14, 1997

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